



**N.J.A.C. TITLE 8  
CHAPTER 33C**

**Certificate of Need and Licensure:  
Regionalized Perinatal Services  
and  
Maternal and Child Health Consortia**

Authority  
N.J.S.A 26:2H-1 et seq.

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**New Jersey Department of Health and Senior Services  
Division of Health Care System Analysis  
Certificate of Need and Acute Care Licensure Program**

**N.J.A.C. 8:33C**  
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## **SUBCHAPTER 1. GENERAL PROVISIONS**

### **8:33C-1.1 Scope and purpose**

(a) The rules contained in this chapter address the certificate of need designation and licensure requirements for a Maternal and Child Health Consortium (MCHC), and for providers seeking and/or requesting a change of the following designation as defined in N.J.A.C. 8:33C- 1.2:

1. Community Perinatal Center-Birth Center;
2. Community Perinatal Center-Basic;
3. Community Perinatal Center-Intermediate;
4. Community Perinatal Center-Intensive; and
5. Regional Perinatal Center.

(b) The purpose of this chapter is to:

1. Set forth certificate of need and licensure requirements for all MCHC.
2. Set forth certificate of need and designation requirements for MCHC members providing perinatal services.
3. Ensure provision of maternal and child health services in a coordinated and cooperative, prevention-oriented manner which is accessible to those in need of care.

### **8:33C-1.2 Definitions**

The following words and terms, when used in this chapter, shall have the following meanings:

“Advanced practice nurse” means a licensed registered professional nurse with certification in a specialty requiring expertise in maternal and child health who has been certified by the New Jersey Board of Nursing, in accordance with N.J.A.C. 13:37-7, Certification of Nurse Practitioners/Clinical Nurse Specialists.

“Back transport” means the act of returning patients to the facility to which they were originally admitted or to their local hospital for further care when the problems that required transport to a higher level facility have been resolved and the patient no longer requires such higher level of care.

“Central service facility” means a health care facility, regulated by the Department, providing essential administrative and clerical support services to two or more direct providers of health care services in a region, which may also include some direct provision of health care services.

“Certified nurse midwife” means a registered professional nurse, licensed as such by the New Jersey State Board of Nursing, who is also a graduate of an accredited school certified by the American College of Nurse Midwives, and licensed as such by the New Jersey Board of Medical Examiners as required through N.J.S.A. 13:35-2A.

“Co-managed” means for two or more providers to temporarily share responsibility for a patient’s health care.

“Commissioner” means the New Jersey State Commissioner of Health and Senior Services.

“Community Perinatal Center” means a designated Community Perinatal Center-Basic, Community Perinatal Center-Birth Center, Community Perinatal Center-Intensive and Community Perinatal Center-Intermediate collectively.

“Community Perinatal Center-Basic” means a licensed general acute care hospital authorized to provide services to neonates and uncomplicated, low risk maternity patients expected to deliver neonates at least 36 weeks in gestational age and weighing greater than 2,499 grams as well as supportive services to infants returned from Regional or Community Perinatal Center-Intensive facilities, as such services are specified within a formal letter of agreement between the facility and a Regional Perinatal Center.

“Community Perinatal Center-Birth Center” means an ambulatory care facility, or a distinct part of a health care facility separately licensed as an ambulatory care facility, authorized to provide routine prenatal and intrapartum care to low risk maternity patients who are expected to deliver neonates at least 37 weeks of gestational age, weighing greater than 2,499 grams, and requiring less than a 24 hour stay following birth.

“Community Perinatal Center-Intensive” means a licensed general acute care hospital authorized to provide services to neonates and complicated maternity patients who are expected to deliver neonates at least 28 weeks of gestational age and weighing greater than 999 grams, as such services are specified within a formal letter of agreement between the facility and a Regional Perinatal Center.

“Community Perinatal Center-Intermediate” means a licensed general acute care hospital authorized to provide services to neonates and complicated maternity patients expected to deliver neonates at least 32 weeks of gestational age and weighing greater than 1,499 grams, as such services are specified within a formal letter of agreement between the facility and a Regional Perinatal Center.

“Consultation” means information or guidance provided by a person recognized as a specialist in a particular medical field. This information may be provided via the telephone or through co-management of the high risk maternal-fetal or neonatal patient.

“Consumer/consumer advocacy organization” means an individual who may receive health care services in a specific health care service region, who is not a health care provider and has no fiduciary interest in a health care service; or, an agency or organization which is not a health care provider and advocates for consumers.

“Department” means the New Jersey State Department of Health and Senior Services.

“General member” means any individual, facility or organization with an interest in maternal and child health who has joined a Maternal and Child Health Consortium.

“High risk” or “patient who is at risk” means any patient identified with a medical/obstetrical condition requiring more than routine medical or surgical intervention.

“High risk infant follow-up” means a system of screening and tracking infants with potentially serious health problems or at risk for developmental delays following discharge from the hospital.

“Hospital” means a New Jersey licensed general acute care hospital.

“Hospital provider” means an individual who is a direct provider of a health care service or has administrative responsibility for a New Jersey licensed general acute care hospital or an individual who is employed by a hospital.

“Hospital service area” means those municipalities in an area determined through the most recent patient origin/market share data collected by the Department to meet one or more of the following criteria:

1. The hospital derives five percent or more of total admissions from the municipality; or
2. Greater than 20 percent of residents of the municipality who are hospitalized utilize the subject hospital; or
3. The hospital is located within the municipality.

“Infant” means a child from birth to one year of age.

“In-hospital coverage” means a system whereby a licensed practitioner is physically present in the hospital as required by N.J.A.C. 8:43G-19.

“Intensive care” means a hospital unit in which special equipment and skilled personnel are concentrated to provide immediate and continuous attention to patients who, because of surgery, shock, trauma, serious injury or life threatening conditions, require intensified comprehensive observation and care.

“Intermediate care” means a hospital unit in which special equipment and personnel are available to care for stable, though ill, patients.

“Intermediate birth weight” means a weight of between 1,500 and 2,500 grams at birth.

“Intrapartum” means the period occurring during childbirth or delivery.

“Labor-delivery-recovery-postpartum (LDRP) bed” means a licensed obstetric bed, the primary function of which is to accommodate an obstetrical patient during the entire course of labor, delivery, recovery, and postpartum periods.

“Letter of agreement” means a document between licensed perinatal and pediatric health care providers and an MCHC, or a document between a Regional Perinatal Center and a Community Perinatal Center, developed in cooperation with the MCHC, which defines the relationship between the parties, specifies all tasks to be provided by each party, and is signed by a representative of each party to the agreement who is authorized to bind the party to such an agreement.

“Low birth weight” means a weight of less than 2,500 grams at birth.

“Maternal and Child Health Consortium” (“MCHC”) means a voluntarily formed nonprofit organization which is licensed as a central service facility by the Department as specified in these rules, and incorporated under Section 501(c)(3) of the United States Internal Revenue Code.

“Maternal and child health service region” means a MCHC’s designated geographically contiguous perinatal and pediatric service delivery area.

“Maternal-fetal transport” means transport of a high risk pregnant patient (that is, a patient diagnosed with a fetal condition which will require stabilization or resuscitation of the infant during the neonatal period, a patient with a severe maternal illness, and other cases in which care by a perinatologist is required) from one facility to another facility able to provide the appropriate level of care.

“Member in good standing” means a MCHC member that has made timely payment of its financial assessment (based on a budget approved by the Department), in accordance with the MCHC’s by-laws.

“Mid-level practitioner” means a certified nurse midwife or advanced practice nurse as set forth in N.J.A.C. 13:35-2A, or a physician assistant as set forth in N.J.A.C. 13:35-2B.

“Neonatal” means the period up to 28 days after birth.

“Neonatal intensive care” means a hospital intensive care unit staffed with specially trained nursing personnel and containing specialized support equipment for treatment of newborn infants who require intensified, comprehensive observation and care exceeding that provided in pediatric acute or newborn nursing units.

“Neonatal transport” means a situation where a team is deployed from one facility to evaluate and stabilize the condition of a neonate at another facility, with the intent of transferring the neonate to the team's facility for a higher level of care, as medically appropriate.

“Neonate” or “newborn” means a child from the moment of birth up to 28 days thereafter.

“Neonatologist” means a physician who is board certified in pediatrics with a certification in neonatology from the American Board of Pediatrics, Sub-Board of Neonatal/Perinatal Medicine or the American Osteopathic Board of Pediatrics, Sub-Board of Neonatology.

“Non-hospital provider” means an individual who is a health care provider or has administrative responsibility for a health care facility but is not employed by a hospital.

“Obstetrician” means a physician who is certified, or eligible for certification by the American Board of Obstetrics and Gynecology, Inc., or the American Osteopathic Board of Obstetrics and Gynecology.

“On-call coverage” means a system whereby a licensed practitioner is readily available to be at the facility within 30 minutes of initial contact as described in N.J.A.C. 8:43G-19.

“Pediatrician” means a physician who is certified or eligible for certification by the American Board of Pediatrics or the American Osteopathic Board of Pediatrics.

“Perinatal” means the period from the 20th week of gestation through the neonatal period.

“Perinatologist” means a physician who is board certified in obstetrics/gynecology with additional certification in maternal-fetal medicine from the American Board of Obstetrics and Gynecology, Inc., Division of Maternal-Fetal Medicine or the American Osteopathic Board of Obstetrics, Sub-Board of Maternal-Fetal Medicine.

“Postpartum” means the period up to, and including 6 weeks following birth.

“Preconceptional care” means assessing an individual for risk factors and counseling the individual prior to pregnancy.

“Prenatal (antepartal)” means the period of fetal development prior to birth.

“Provider” means an individual who is a provider of health care either directly through the provision or administration of health services or indirectly by having a fiduciary interest in such services.

“Referral” means a situation where the attending physician transfers the responsibility of the patient’s care to a physician specializing in either neonatal or maternal-fetal medicine at the Regional Perinatal Center. Such a transfer of responsibility can consist of consultation only with the attending physician retaining care responsibility or continued management by the Regional Perinatal Center through delivery.

“Regional Perinatal Center” means a general acute care hospital which is designated and licensed to provide care to high risk mothers and neonates. Such a facility provides consultation, referral, transport and follow-up to other members of its Maternal and Child Health Consortium.

“Regional perinatal and pediatric plan” means the three year plan developed and updated annually by the existing or proposed MCHC, which describes how prenatal, intrapartum, newborn and infant follow-up services and pediatric services are delivered in the maternal and child health service region, as well as strategies for improving services.

“Regional transport system” means a system developed by the MCHC which includes written policies and procedures for the triage of mothers and/or infants to the most appropriate level of care in accordance with formal letters of agreement.

“Regionalized services” means services which are planned and delivered within a specific geographic zone for the best use of financial and medical resources such as staffing, equipment, facilities, education and expertise to coordinate appropriate quality health care to a specific population.

“Risk reduction services” means specific perinatal addiction prevention and intervention services which may be provided individually or on a regional basis in accordance with the guidelines established by the Department.

“Risk reduction specialist” means a registered professional nurse, a licensed or certified social worker, or other professional in a maternal and child health addiction-related field who has specialized training and experience in perinatal addiction.

“Total quality improvement program” means an ongoing and systematic process designed to review, measure and evaluate quality of care and perinatal and pediatric outcomes.

“Transfer” means a temporary or permanent shift in responsibility for a patient’s health care management from one provider to another.



“Transport” means the process whereby the attending physician or certified nurse midwife at the Birth Center or Community Perinatal Center determines that the status of the patient has become acutely high risk and arranges for the transfer of the patient to a higher level facility, and includes maternal-fetal and/or neonatal transport.

“Ventilatory support” means the application of positive pressure ventilation and oxygen through mechanical devices, including continuous positive airway pressure (CPAP).

“Very low birth weight” means a weight of less than 1,500 grams at birth.

### **8:33C-1.3 Certificate of need**

(a) In accordance with N.J.S.A. 26:2H-1 et seq., and amendments thereto, a MCHC or perinatal services shall not be instituted, constructed or expanded except upon application for, and receipt of, a certificate of need issued by the Commissioner in accordance with this chapter, N.J.A.C. 8:33 and N.J.S.A. 26:2H-1 et seq.

(b) Certificate of need applications and instructions for completion pursuant to N.J.A.C. 8:33 and this chapter may be obtained from:

New Jersey State Department of Health and Senior Services  
Certificate of Need and Acute Care Licensure  
P.O. Box 360, Room 604  
Trenton, New Jersey 08625-0360

(c) The Commissioner may place conditions upon an applicant’s certificate of need approval, and such conditions shall become part of the licensure requirements applicable to the applicant upon implementation of the certificate of need and licensure.

(d) Applicants shall implement all conditions imposed by the Commissioner as specified in the certificate of need approval letter. Failure to implement the conditions may result in action by the Commissioner, commensurate with the requirements set forth at N.J.A.C. 8:33-4.16.

### **8:33C-1.4 Submission of certificate of need applications**

(a) No person shall establish a MCHC prior to submission and full review pursuant to N.J.A.C. 8:33-4.1(a) of a certificate of need application.

(b) No hospital shall engage in any of the activities specified in (b)1 through 4 below until it has submitted a certificate of need for full review pursuant to N.J.A.C. 8:33-4.1(a), and received approval thereof.

1. Changes in its membership in a MCHC;
2. Establishment and designation of new services as a Regional Perinatal Center, Community Perinatal Center-Intensive and Community Perinatal Center-Intermediate;
3. Changing its perinatal designation to Regional Perinatal Center, Community Perinatal Center-Intensive and Community Perinatal Center-Intermediate; or
4. Increase(s) in the number of intermediate or intensive bassinets.

(c) A provider shall submit certificate of need subject to expedited certificate of need review in accordance with N.J.A.C. 8:33-5.1 et seq. prior to:

1. Establishment and designation of new perinatal services as a Community Perinatal Center-Basic; or
2. Establishment and designation of new perinatal services as a Community Perinatal Center-Birth Center.

(d) All MCHC applicants shall develop a regional perinatal and pediatric plan, as that term is defined in N.J.A.C. 8:33C-1.2, which shall be submitted with the certificate of need application.

(e) Applicants seeking establishment and designation as a Regional Perinatal Center, Community Perinatal Center-Intermediate, or Community Perinatal Center-Intensive shall submit their certificate of need applications in accordance with the most recent regional perinatal and pediatric plan applicable to the applicant's MCHC membership.

#### **8:33C-1.5 Data reporting requirements of certificate of need applicants**

(a) The proposed MCHC shall submit formal letters of agreement valid for at least five years as follows:

1. Between each facility licensed to provide perinatal or pediatric services and the MCHC; and
2. Between each facility licensed to provide perinatal or pediatric services and the Regional Perinatal Center.

(b) All Regional and Community Perinatal Center certificate of need applicants shall document the ability to comply with the following data reporting requirements for submission to the Department and the appropriate MCHC:

1. B2 Quarterly Inpatient Utilization Reports in accordance with N.J.A.C. 8:31B, which include data pertaining to maintained beds and bassinets, admissions, births, transfers and total patient days;
2. New Jersey Department of Health and Senior Services Electronic Birth Certificate system, as required by N.J.S.A. 26:8-2.8 and N.J.A.C. 8:2; and
3. Other anonymous case review reports and data, as requested by the Department.

(c) All Regional and Community Perinatal Center certificate of need applicants shall provide, as requested by the Department and the MCHC, individual patient data, compiled from the comprehensive patient record, in furtherance of State and regional total quality improvement monitoring.

## **SUBCHAPTER 2. MATERNAL AND CHILD HEALTH CONSORTIA**

### **8:33C-2.1 Establishment of maternal and child health service regions**

(a) Every MCHC shall have a designated maternal and child health service region which shall define the scope of the MCHC's coverage area.

(b) To be designated as a maternal and child health service region, a region must include all of the following:

1. A distribution of perinatal and pediatric providers within a geographically contiguous region that will enable the development of a rational and cohesive network of services, in accordance with the requirements set forth in this chapter.
2. A sufficient network of hospital members, with a three-year documented history of transfer relationships, to deliver a minimum of 10,000 women a year. The MCHC shall demonstrate conformity with these volume criteria by using data provided by the Department for the last three consecutive years of data available or the most recent year which is consistently applied to the review of all certificate of need applications within a region. The Commissioner may, at his or her discretion, grant a waiver to the delivery requirement of 10,000 women a year, if the applicant has been able to provide quantifiable evidence of severe problems of access to needed perinatal services due to geographic isolation. However, in no case will a waiver be granted where the number of deliveries is below 8,000 women per year.
3. At least one hospital in the region designated as a Regional Prenatal Center plus a geographically balanced distribution of Community Prenatal Centers of all levels.

### **8:33C-2.2 Membership of the Maternal and Child Health Consortia**

(a) Any organization, facility or individual with an interest in maternal and child health within the MCHC service region shall be eligible to join a MCHC as defined at N.J.A.C. 8:33C-1.2. General membership from within the maternal and child health service region shall include, but not be limited to:

1. All licensed hospitals with obstetric and/or pediatric services and birth centers; and
2. All licensed ambulatory care facilities which provide prenatal care, and care to infants and families with children up to age 21;
3. Professional organizations, nonprofit organizations, local or county governmental agencies, home health agencies and any other organization or individual concerned with the needs of families with infants, children and adolescents, including those with special health care needs;

4. Health maintenance organizations, managed care providers and other insurers; and
5. Community and consumer organizations.

(b) No hospital providing perinatal or pediatric services shall change membership from one MCHC service region to another unless the proposed MCHC service region is geographically contiguous to the county in which the hospital is located. The change in membership shall occur no less than one year from the date of submission of an approved certificate of need for change in membership. The hospital shall sign a letter of agreement valid for at least five years specific to membership in the new MCHC. The letter of agreement shall accompany the certificate of need application and may contain a contingency clause that indicates that it shall be effective on the date the Commissioner approves the application.

(c) Hospitals providing perinatal or pediatric services shall be members in good standing of a MCHC and shall sign a letter of agreement valid for at least five years specific to membership in the MCHC. The letter of agreement process shall be specified in the MCHC's policy and procedures and the MCHC shall maintain such letters on file and forward copies to the Department upon execution.

### **8:33C-2.3 Governance of the Regional Maternal and Child Health Consortia**

(a) All members within a maternal and child health service region which agree to associate and apply to become a MCHC, shall formally establish a nonprofit corporation consistent with the Internal Revenue Code, as set forth in 26 U.S.C. §501(c)(3).

(b) The non-profit organization established in accordance with (a) above shall develop by-laws, voted upon by the general membership, which will establish participatory governance by all members and will establish and define the specific composition of a Board of Directors or Trustees. Each member agency shall have one vote in the nonprofit organization. Individual members, employed by a member agency, shall not be permitted to vote as individual members.

(c) The Board of Directors or Trustees shall be nominated from and voted upon by the general membership. The Board shall consist of a minimum of 18 members, one-third of which shall be hospital providers, one-third of which shall be non-hospital providers and one-third of which shall be consumers/consumer advocacy organizations. The racial/ethnic composition of the maternal and child health service region as well as an appropriate number of agencies concerned with women's reproductive health and the needs of pregnant women, infants, young children, adolescents, and children with special needs, shall be reflected in the membership of the MCHC Board of Directors or Trustees. At least two members shall be physicians, holding a current New Jersey license, one who is board eligible or certified in obstetrics, and one who is board eligible or certified in pediatrics. At least one member shall be a registered professional nurse, holding a current New Jersey license with a certification in either maternal and child health nursing or in community health nursing. At least one member shall be a health officer, as defined in N.J.A.C. 8:52-1.4.

**8:33C-2.4 Budget requirements of the Maternal and Child Health Consortia**

Each MCHC certificate of need applicant shall submit a budget plan for the first complete year of operation which links all projected salary and non-salary costs to the required activities as described in N.J.A.C. 8:33C-2.5, 5.1 (required services), and 7.3 (staffing requirements). subsequent to certificate of need approval, a projected budget, including the Board approved formula for distribution of the allocated or assessed amount to be paid by member hospitals, shall be provided annually by the MCHC to the Department for review and approval.

**8:33C-2.5 Staffing requirements of the Regional Maternal and Child Health Consortia**

Each MCHC applicant shall document the ability to recruit, at a minimum, staffing levels in accordance with the MCHC licensure standards, as set forth at N.J.A.C. 8:33C-7.3.

**8:33C-2.6 Functions of the Regional Maternal and Child Health Consortia**

(a) MCHC certificate of need applications shall include documentation of the ability to provide the following services, consistent with the MCHC licensure standards, as set forth in this chapter:

1. A regional perinatal and pediatric plan;
2. A region-wide system for on-going total quality improvement;
3. A system for the provision of regional professional and consumer education;
4. A regional perinatal transport system; and
5. A system for the provision of infant follow-up services.

**8:33C-2.7 Regional perinatal and pediatric plan**

(a) Each MCHC certificate of need applicant shall submit a regional perinatal and pediatric plan to the Department for approval, with projections for the following three years, as the basis for the establishment of the consortium. The regional perinatal and pediatric plan shall include each of the components listed in (b) below, and shall be updated and approved by the Department annually.

(b) The specific components of the regional perinatal and pediatric plan shall include the following:

1. A needs assessment which describes the current status of the maternal and child health services region with respect to: the occurrence of infant mortality; low birth weight births; the proportion of women receiving risk appropriate prenatal care; number of births to adolescents; the occurrence of pediatric mortality and morbidity for children from birth to

- 21 years of age; and social, cultural, economic and demographic factors influencing the perinatal and pediatric needs of the communities served by the maternal and child health service region;
2. A description of current perinatal and pediatric services in the region, including Medicaid managed care providers. This description shall include a list, by county, of all of the following:
    - i. Practicing obstetric, prenatal care and family planning providers;
    - ii. Practicing perinatal specialists, both nursing and medical;
    - iii. Practicing pediatric care providers, including family practice, primary care providers, and specialists serving children from birth to 21 years of age;
    - iv. A list of sites, both licensed ambulatory and private practice, where preconceptional health, family planning, genetic counseling, prenatal care, school based youth services, local government (child health conferences), pediatric primary care, pediatric long term care, pediatric rehabilitation services, mental health services, early intervention programs, child evaluation centers, and other specialized services are provided;
    - v. A description, by hospital, of the existing inpatient maternity, newborn and pediatric services to include all of the following:
      - (1) The number of traditional labor, delivery, recovery and postpartum beds, and/or the number of multi-function rooms, i.e. labor-delivery-recovery or labor-delivery-recovery-postpartum rooms;
      - (2) Licensed intermediate care bassinet capacity and utilization;
      - (3) Licensed intensive care bassinet capacity and utilization;
      - (4) Licensed pediatric bed capacity and utilization;
      - (5) Licensed pediatric intensive care bed capacity and utilization;
      - (6) The number of pediatric admissions to hospitals without licensed pediatric beds;
      - (7) The number of pediatric patients admitted for ambulatory care sensitive diagnoses; and

- (8) Documentation of the appropriate in-house and on-call coverage commitments by professional staff for ambulatory, emergency department and inpatient services in each facility;
- vi. A list of sites where high-risk infant follow-up programs are provided; and
- vii. A list of hospitals designated by the Department as Level I or Level II trauma centers;
- 3. An assessment of gaps in services developed by comparing the identified needs described in (b)1 above, with the current resources described in (b)2 above. A description of the potential need for new services or changes in the distribution of existing services within the region shall also be included;
- 4. A list of objectives that address identified gaps in existing hospital and community services within the region, and measurable outcome criteria and methods to achieve those objectives.
- 5. A plan that describes the use of mid-level practitioners, such as obstetric and pediatric nurse practitioners, family planning nurse practitioners, certified nurse midwives, other advanced practice nurses, and physician assistants, especially in areas of assessed provider shortages;
- 6. A prevention plan that describes both clinical (inpatient and ambulatory) and nonclinical services to be provided to mothers and families in the maternal and child health service region (both at risk and general) to help reduce the incidence of identified behaviorally-based perinatal problems, and includes a comprehensive risk assessment protocol;
- 7. A plan to assure access to culturally sensitive, community-based, preventive and primary services by all children that includes well-child and 24 hour sick care; and
- 8. A plan to develop an infant tracking system of all newborns in need of primary care.



**8:33C-2.8 Projection of need for intermediate and intensive bassinets**

(a) The MCHC regional perinatal plan shall identify the current need for intensive bassinets as determined by the Department through use of the following methodology.

$$\frac{(axb)+(cxd)+(exf)+(gxh)+(ixj)+(kxl)+(mxn)+(oxp)}{365} \times 1.18$$

where

- a = Regional number of live births < 1,000 grams discharged alive plus the regional number of live births 1,000 to 1,500 grams with a significant operating room procedure discharged live
- b = Statewide average length of stay for patient type defined in a above
- c = Regional number of live births < 1,500 grams not included in a above
- e = Regional number of live births > or = 1,500 grams but < 2,500 grams with a significant operating room procedure with major multiple problems
- f = Statewide average length of stay for type of patients described in e above
- g = Regional number of live births > or = 1,500 grams but < 2,000 grams either (1) with a significant operating room procedure, but without multiple major problems or (2) without a significant operating room procedure, but with multiple major problems
- h = Statewide average length of stay for patients described in g above
- i = Regional number of live births > or = 2,000 grams but < 2,500 grams either (1) with a significant operating room procedure, but without multiple major problems or (2) without a significant operating room procedure, but with multiple major problems
- j = Statewide average length of stay for patients described in i above
- k = Regional number of live births > or = 1,500 grams but < 2,500 grams with a major problem, but without a significant operating room procedure
- n = Statewide average length of stay for patients described in m above
- o = Regional number of live births > or = 2,500 grams with a significant operating room procedure and multiple major problems.
- p = Statewide average length of stay for patients described in o above

(b) The MCHC shall determine the need for intermediate bassinets in accordance with the methodology developed by the MCHC and identified in its approved regional perinatal and pediatric plan.

(c) The MCHC shall project the need for intensive and intermediate bassinets for the next four years as follows:

1. For the number of intermediate birth weights and very low birth weights, the MCHC shall use the average data reported to the Department for the two years prior to the certificate of need submission.

2. For the Statewide average length of stay per birth weight category, the MCHC shall use the Statewide average length of stay most recently determined by the Department most recent to the date of the certificate of need review process.

#### **8:33C-2.9 Distribution of intermediate and intensive bassinets**

(a) Regional Perinatal Centers or Community Perinatal Centers-Intensive shall provide neonatal intensive care. The final allocation of such bassinets shall be made by the Commissioner through the certificate of need review process.

(b) The minimum size of any neonatal intensive care unit shall be six bassinets. The minimum size of any neonatal intermediate care unit shall be four bassinets. Waiver of the minimum size of a neonatal intermediate care unit may be obtained from the Commissioner in cases where geographic inaccessibility is demonstrated and where no additional costs will be incurred. Waiver of the minimum size of a neonatal intensive care unit is not available and none shall be granted. Applicants seeking a waiver shall follow the process set forth at N.J.A.C. 8:33C-4.4(c).

#### **8:33C-2.10 Regional professional and consumer education**

The MCHC certificate of need application shall describe planned actions for providing or coordinating an ongoing program of professional and consumer education which covers the maternal and child health service region.

#### **8:33C-2.11 Total quality improvement program**

The MCHC certificate of need application shall describe planned actions for establishing a total quality improvement plan which includes all components specified in the MCHC licensure standards, as set forth at N.J.A.C. 8:33C-5. The plan shall include the development of fetal, infant and child death review systems in coordination with the Department. The regional total quality improvement plan, and any subsequent modification(s) thereof, shall be reviewed and approved by the Department prior to implementation.

#### **8:33C-2.12 Regional maternal-fetal and neonatal transport system**

The MCHC certificate of need application shall describe a plan for a regional maternal-fetal and neonatal (perinatal) transport system in accordance with N.J.A.C. 8:43G-19. The transport plan shall be reviewed and approved by the Department subsequent to approval of the MCHC certificate of need application in accordance with the provisions set forth at N.J.A.C. 8:33C-5.1.

#### **8:33C-2.13 Infant follow-up**

The MCHC application shall describe a system for appropriate discharge planning and infant follow-up in accordance with the licensure standards at N.J.A.C. 8:33C-5.

## **SUBCHAPTER 3. CERTIFICATE OF NEED REVIEW CRITERIA**

### **8:33C-3.1 MCHC certificate of need application review criteria**

(a) Certificate of need applications for MCHC shall be reviewed on the basis of the following criteria:

1. Full compliance with all standards set forth in this chapter;
2. Full compliance with methods for addressing existing gaps in services and barriers to care identified in the most recent regional perinatal and pediatric plan;
3. Full compliance with methods identified in the most recent regional perinatal and pediatric plan, to promote access to preconceptional, prenatal, intrapartum, postpartum, family planning and pediatric services by all women and infants in the region, including Medicaid beneficiaries and those who are medically indigent; and
4. Development of the most cost effective linkages with existing hospital and community-based providers.

### **8:33C-3.2 Facility certificate of need application review criteria**

(a) Certificate of need applications submitted by a hospital proposing to provide or expand intermediate or intensive care to pregnant women and/or newborns and requesting designation shall be reviewed on the basis of the following:

1. The existence of need for the proposed service in the community, as stated in the most recent regional perinatal and pediatric plan, in accordance with the appropriate formula as specified in accordance with the need methodology set forth at N.J.A.C. 8:33C-2.8(a) or (b), as appropriate;
2. That the hospital is in full compliance with the rules set forth in this chapter, the rules set forth at N.J.A.C. 8:33, N.J.A.C. 8:33A, and N.J.A.C. 8:43G-5.10, as well as compliance with N.J.S.A. 26:2H-18 et seq.;
3. That the certificate of need applicant has become a general member or is a member in good standing of a MCHC;
4. Documentation that the certificate of need applicant has notified the appropriate MCHC of the change in services planned in accordance with the application; and

5. The certificate of need applicant's intent and ability to assure access to patient care services as required through N.J.A.C. 8:33, and 8:33A.

(b) Certificate of need applications submitted by an acute care hospital proposing to provide care to uncomplicated maternity and normal newborn patients, and requesting designation as a Community Perinatal Center-Basic, shall be reviewed on the basis of the following:

1. That the hospital is in full compliance with the rules set forth at N.J.A.C. 8:33-5;
2. That the certificate of need applicant has become a general member or is a member in good standing of a MCHC;
3. Documentation that the certificate of need applicant has notified the appropriate MCHC of the services planned in accordance with the application; and
4. The certificate of need applicant's intent and ability to assure access to patient care services as required through N.J.A.C. 8:33.

(c) Certificate of need applications submitted by a facility proposing to provide routine uncomplicated intrapartum care to pregnant women and/or their babies and requesting designation as a Community Perinatal Center-Birth Center shall be reviewed on the basis of the following:

1. That the facility is in full compliance with the rules set forth at N.J.A.C. 8:33-5;
2. That the certificate of need applicant has become a general member or is a member in good standing of a MCHC;
3. Documentation that the certificate of need applicant has notified the appropriate MCHC of the services planned in accordance with the application; and
4. The certificate of need applicant's intent and ability to assure access to patient care services as required through N.J.A.C. 8:33.

### **8:33C-3.3 Certificate of need application requirements**

(a) An acute care hospital seeking a change in membership from one MCHC to another shall submit a certificate of need application to the Department which shall document all of the following:

1. Evidence of notification to the MCHC that the applicant is leaving and the reasons for same;
2. Impact on service delivery in the MCHC that the applicant is leaving;
3. Evidence from the new MCHC that the applicant will be accepted into its region; and

4. Impact on service delivery in the MCHC in which the applicant is requesting membership.

(b) A hospital proposing to provide or expand intermediate or intensive care to pregnant women and/or their newborns shall submit a certificate of need application to the Department which shall document all of the following:

1. Number and occupancy rates of its labor, delivery, recovery and postpartum beds and/or of multi-function rooms for the preceding two years and a projection of the needs for the next four years;
2. Number and occupancy rates of its currently licensed bassinets for the two years immediately preceding the certificate of need submission, and a projection of the needs for the next four years;
3. Number of maternal-fetal and neonatal referrals and transports the applicant has made to a facility designated and licensed for advanced capabilities for the preceding two years and a projection of the needs for the next four years;
4. Consistency of the application with the needs of the community, as described in the regional perinatal and pediatric plan in effect at the time of the certificate of need application submission. A waiver to the regional perinatal and pediatric plan may be considered in accordance with N.J.A.C. 8:33C-4.4 (c), based on an updated analysis of individual facility or regional occupancy rates and acuity levels as documented by the applicant and the MCHC.
5. A mechanism for providing or assuring access to ambulatory prenatal, postpartum, normal newborn and pediatric care, and drug and alcohol risk reduction services which are located within the hospital service area or on site as specified in N.J.A.C. 8:43G-19. Maternity and pediatric services shall be provided in accordance with N.J.A.C. 10:54-6, HealthStart-Maternity and Pediatric Care Services;
6. Documentation of use by all providers on staff of a comprehensive perinatal record as approved by the MCHC, such as, but not limited to the American College of Obstetricians and Gynecologists perinatal record;
7. That the hospital and the MCHC will enter into a letter of agreement stating that the hospital shall be a member of the MCHC for no less than five years. A draft copy of the letter of agreement shall be submitted with the certificate of need application;
8. Letters of agreement specific to coordination of services, transports and referrals as follows:

- i. If a region contains more than one hospital designated and licensed as a Regional Perinatal Center, cooperative letters of agreement valid for at least five years shall be developed and adopted between the Regional Perinatal Centers. The Regional Perinatal Centers shall then develop and adopt letters of agreement with the Community Perinatal Centers, accordingly. These letters of agreement valid for at least five years shall be facilitated by the MCHC and comply with the regional transport system, established in accordance with N.J.A.C. 8:33C-5.1(c);
  - ii. The letters of agreement shall specify that any patient requiring specialized perinatal or neonatal care shall be referred to a provider with privileges at a Community Perinatal Center-Intensive, or a Regional Perinatal Center as specified in the regional perinatal and pediatric plan, and in accordance with N.J.A.C. 8:43G-19; and
  - iii. Maternal-fetal and neonatal transports shall be provided by the Community Perinatal Centers only if these services are approved activities delineated in the letter of agreement with the Regional Perinatal Center and are in compliance with N.J.A.C. 8:43G-19 and the approved regional transport system for that MCHC.
9. A description of the method of management for patients assessed to be at risk during the prenatal period using a comprehensive risk assessment tool, which shall include referral to a provider with advanced capabilities in maternal-fetal medicine for initial consultation and appropriate follow-up; and
10. Compliance with N.J.S.A. 26:2H-18 et seq.

#### **8:33C-3.4 Designation-specific certificate of need documentation**

(a) In addition to the requirements specified in N.J.A.C. 8:33C-3.2(a) and 3.3(b), certificate of need applicants seeking designation as Regional Perinatal Centers shall provide the following additional information;

1. Documentation that the following minimum volume requirements shall be met within two years of initiation of the service:
  - i. Annual acceptance of over 80 maternal-fetal referrals or transports; and
  - ii. Provision of full neonatal case management to over 40 very low birth weight infants annually;
2. Demonstration of the need for intensive care bassinets, in accordance with the methodology set forth at N.J.A.C. 8:33C-2.8(a) and in accordance with the regional perinatal and pediatric plan in effect at the time of the certificate of need application submission;

3. Documentation of the capability to provide, on a continuous basis, care for high risk mothers who have a broad spectrum of conditions, including preexisting maternal disorders, such as significant heart, renal or metabolic diseases, chronic infectious diseases, substance abuse, as well as major complications of pregnancy.
4. Documentation of the ability to care for high risk newborns of very low birth weight, in need of complex neonatal respiratory and metabolic support, or other infants in need of major medical or surgical intervention in accordance with N.J.A.C. 8:43G-19.
5. Documentation of the capability to provide the full range of antenatal testing, prenatal, postpartum and infant and pediatric health services to families in the region. The applicant shall document the existence of a distinct prenatal clinic service in accordance with the requirements as set forth in N.J.A.C. 8:43G-19.
6. Documentation of the existence of, or capability to initiate, a high risk prenatal clinic which is, or shall be staffed, at a minimum, by the following:
  - i. A perinatologist who shall be responsible for the direction of care provided to patients of the clinic and available to provide consultation to the attending physicians;
  - ii. An advanced practice nurse on site; and
  - iii. A risk reduction specialist.
7. Documentation that high risk infant follow-up services shall be provided. Guidelines, compliance with which is not mandatory, are available from the Department of Health and Senior Services, Regional Services Program, PO Box 364, Trenton, New Jersey 08625-0364, telephone (609) 292-5616.
8. Documentation of 24 hour availability of a perinatologist to provide consultation to the attending physicians at Community Perinatal Centers. Consultation shall be provided through referral, co-management, transfer or transport;
9. Documentation of a regional transport system established in accordance with N.J.A.C. 8:33C-5.1(c) and with N.J.A.C. 8:43G-19, and the letters of agreement with the Community Perinatal Centers in the region; and
10. Documentation that a full range of risk reduction services shall be provided. Guidelines, compliance with which is not mandatory, are available from the Department of Health and Senior Services, Regional Services Program, PO Box 364, Trenton, New Jersey 08625-0364, telephone (609) 292-5616.

(b) In addition to the requirements specified in N.J.A.C. 8:33C-3.2(a) and N.J.A.C. 8:33C-3.3(b), certificate of need applicants seeking designation as a Community Perinatal Center-Intensive shall provide the following additional information:

1. Demonstration of the need for intensive care bassinets, in accordance with the methodology set forth at N.J.A.C. 8:33C-2.8(a) and in accordance with the regional perinatal and pediatric plan in effect at the time of the certificate of need submission.
2. A description of the process for assuring that maternal-fetal transports of patients with needs exceeding the facility's capabilities shall be made as soon as possible, to a facility designated and licensed to provide the appropriate level of care, in accordance with the approved regional transport system, the letters of agreement, and N.J.A.C. 8:43G-19.
3. A description of the process for assuring that any high risk infant delivered at the Community Perinatal Center-Intensive, in need of specialized services or services which exceed the facility's capabilities, shall be transported as soon as possible to a facility designated and licensed to provide the appropriate level of care as specified in the terms of the approved regional transport system, the letters of agreement, and N.J.A.C. 8:43G-19.
4. Documentation of a mechanism for providing or assuring access to high risk infant follow-up services. Guidelines, compliance with which is not mandatory, are available from the Department of Health and Senior Services, Regional Services Program, PO Box 364, Trenton, New Jersey 08625-0364, telephone (609) 292-5616.

(c) In addition to the requirements specified in N.J.A.C. 8:33C-3.2(a) and N.J.A.C. 8:33C-3.3(b), certificate of need applicants seeking designation as a Community Perinatal Center-Intermediate shall provide the following additional information:

1. Demonstration of the need for intermediate care bassinets utilizing the methodology set forth at N.J.A.C. 8:33C-2.8(b) and in accordance with the regional perinatal and pediatric plan in effect at the time of the certificate of need submission.
2. A description of the process for assuring that maternal-fetal and/or neonatal transports for patients whose needs exceed the facility's capabilities shall be made, as soon as possible to a facility designated and licensed to provide the appropriate level of care in accordance with the approved regional transport system, the letters of agreement, and N.J.A.C. 8:43G-19.
3. A description of the process for assuring that any high risk infant anticipated to require ventilatory support longer than forty-eight hours (cumulative or otherwise), with needs exceeding the facility's capabilities shall be transported as soon as possible after delivery to a facility designated and licensed to provide the appropriate level of care in accordance with the approved regional transport system, the letters of agreement, and N.J.A.C. 8:43G-19.



(d) In addition to the criteria at N.J.A.C. 8:33C-3.2(b), certificate of need applicants seeking designation as a Community Perinatal Center-Basic shall provide all of the following additional information in their certificate of need applications:

1. Documentation that the applicant shall provide care to patients expected to deliver neonates of a weight greater than 2,499 grams and at least 36 weeks gestational age;
2. Documentation that the applicant shall provide supportive care for infants returned from Regional or Community Perinatal Center-Intensive facilities;
3. That the hospital and the MCHC will enter into a letter of agreement stating that the hospital shall be a member of the MCHC for no less than five years. A draft copy of the letter of agreement shall be submitted with the certificate of need application; and
4. Letters of agreement valid for at least five years specific to coordination of services, transports and referrals shall be developed and adopted between a Community Perinatal Center-Basic and a designated and licensed Community Perinatal Center-Intensive or Regional Perinatal Center. These letters of agreement shall be facilitated by the MCHC and comply with the regional transport system, as described in this chapter and N.J.A.C. 8:43G-19; and
5. Number of maternal-fetal and neonatal referrals and transports the applicant has made to a facility designated and licensed for advanced capabilities for the preceding two years and a projection of the needs for the next four years.

(e) In addition to the criteria specified at N.J.A.C. 8:33C-3.2(c), certificate of need applicants seeking designation as a Community Perinatal Center-Birth Center shall provide all of the following additional information in their certificate of need applications:

1. Documentation that the applicant shall provide care to patients expected to deliver neonates of a weight greater than 2,499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth;
2. That the hospital and the MCHC will enter into a letter of agreement stating that the hospital shall be a member of the MCHC for no less than five years. A draft copy of the letter of agreement shall be submitted with the certificate of need application; and
3. Letters of agreement valid for at least five years specific to coordination of services, transports and referrals shall be developed and adopted between Community Perinatal Center-Birth Center and at a minimum, a designated and licensed Community Perinatal Center-Intermediate, located within 20 minutes transport time for medical care of a woman or an infant when complications arise during the antepartum, intrapartum, postpartum or newborn period.

(f) Designated specialty acute care children's hospitals, as specified in N.J.S.A. 26:2H-18a, 18c, 18d and 18e, shall provide highly specialized regional neonatal care. Certificate of need applicants must document in their certificate of need applications:

1. The ability to meet the criteria for the provision of neonatal services required of the Regional Perinatal Center including 24 hour a day, seven days a week, in-hospital coverage by a neonatologist, except that specialty acute care children's hospitals shall not be required to provide obstetric services; and
2. The capability of performing sub-specialty surgical procedures, and acting in a leadership role in providing the most recent technology in neonatal medicine and to the medical community throughout the State.

#### **8:33C-3.5 Relationship between licensure and certificate of need requirements**

The provisions of N.J.A.C. 8:43G Licensing Standards for Hospitals and N.J.A.C. 8:43A Standards for Licensure of Ambulatory Care Facilities are hereby incorporated by reference. Applicants receiving certificate of need approval under the provisions of this chapter shall comply with all applicable licensing requirements of N.J.A.C. 8:43G, and N.J.A.C. 8:43A.

## **SUBCHAPTER 4. MATERNAL AND CHILD HEALTH CONSORTIA LICENSURE REQUIREMENTS**

### **8:33C-4.1 Application for licensure**

(a) Following receipt of a Certificate of Need, any person, organization, or corporation desiring to operate a MCHC shall make application to the Commissioner for licensure on forms prescribed by the Department, in accordance with the requirements set forth in this chapter. Operation of the MCHC shall not commence until the license is issued. Every MCHC shall apply for licensure renewal annually. Licensure application forms may be obtained from:

Director  
Certificate of Need and Acute Care Licensure  
Division of Health Care Systems Analysis  
New Jersey State Department of Health and Senior Services  
P.O. Box 360  
Trenton, New Jersey 08625-0360

(b) The applicant shall submit to the Department a non-refundable fee of \$1000.00 for the filing of an application for licensure of a MCHC and for each annual renewal of the license and for a transfer of ownership.

(c) Each maternal and child health consortia shall be assessed a biennial inspection fee of \$400.00. For existing facilities, this fee shall be assessed in the year the facility will be inspected, along with the annual licensure fee for that year. The fee shall be added to the initial licensure fee for new facilities. Failure to pay the inspection fee shall result in non-renewal of the license for existing facilities and the refusal to issue an initial license for new facilities. This fee shall be imposed only every other year even if inspections occur more frequently and only for the inspection required to either issue an initial license or to renew an existing license. It shall not be imposed for any other type of inspection.

### **8:33C-4.2 Licensure**

(a) The Department shall issue a license to a regional MCHC when the applicant demonstrates it is in compliance with the provisions set forth in N.J.S.A. 26:2H-1 et seq., the requirements set forth in this chapter and all other applicable licensure standards.

(b) The Department shall renew a MCHC's license annually on the original licensure date, or within 30 days thereafter, but dated back to the original licensure date, following receipt of the required licensure fee from the MCHC, if the MCHC continues to be in compliance with all licensure and certificate of needs standards applicable to it.

1. The Department shall issue a statement for the required licensure fee to the MCHC at least 30 days prior to the MCHC's annual licensure renewal date.
2. The Department shall not issue a renewal license to an MCHC if its license has been suspended or revoked prior to the annual license renewal date.

(c) The license shall be conspicuously posted in the main office of the MCHC.

(d) The license shall not be assignable or transferable, and it shall be void immediately if the MCHC ceases to operate.

#### **8:33C-4.3 Surrender of license**

(a) The MCHC shall notify the Department at least 30 days prior to the voluntary surrender of a license. Whenever a license is subject to voluntary surrender, revocation, non-renewal, or suspension it shall be returned to the Certificate of Need and Acute Care Licensure Program of the Department within seven working days after the voluntary surrender, revocation, non-renewal, or suspension.

(b) If the MCHC plans to cease operation, within seven working days after the MCHC ceases operation it shall notify the Department of the location where records shall be stored and of methods for their retrieval within 10 business days.

#### **8:33C-4.4 Waiver**

(a) The Commissioner or his or her designee, in accordance with the general purposes and intent of N.J.S.A. 26:2H-1 et seq., and the rules in this chapter, may waive sections of these rules pertaining to licensure requirements if, in his or her opinion, such waiver would not endanger the life, safety, or health of patient(s) or the public and failure to grant such waiver would result in undue hardship to the applicant.

(b) A MCHC seeking a waiver of the licensure rules shall apply in writing to the Director of the Certificate of Need and Acute Care Licensure Program of the Department.

(c) A written request for waiver shall include all of the following:

1. The specific rule(s) or part(s) of the rule(s) for which waiver is requested;
2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the MCHC if a waiver is not approved;
3. An alternative proposal which would ensure patient health, safety and welfare; and
4. Documentation to support the request for waiver and the reasons submitted therefor.

(d) The Department, in its discretion, may request additional information before processing a request for waiver, as needed. Failure to supply the requested information may result in denial of the application for waiver.

#### **8:33C-4.5 Action against a licensee**

If the Department determines that operational deficiencies exist which may cause the MCHC to be out of compliance with this chapter and/or any other applicable rules and regulations, the Department may require that all services or a portion thereof, provided within the MCHC cease. This may be done simultaneously with, or in lieu of, action to revoke licensure and/or impose a fine. The Commissioner or his or her designee shall notify the MCHC in writing of such determination, including the reasons therefor.

#### **8:33C-4.6 Hearings**

If the Department proposes to suspend, revoke and/or impose other lawful remedies, the licensee may request a hearing which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

#### **8:33C-4.7 Relocation**

An MCHC that relocates, voluntarily or involuntarily, shall submit a licensing application for review and approval to the Department, along with a nonrefundable fee of \$250.00, prior to its relocation.

#### **8:33C-4.8 Transfer of Ownership**

An MCHC that transfers ownership, voluntarily or involuntarily, shall submit a licensing application for review and approval by the Department, with a nonrefundable fee of \$1000.00 prior to any transfer of ownership.

## **SUBCHAPTER 5. MINIMUM REQUIREMENTS FOR LICENSURE OF MATERNAL AND CHILD HEALTH CONSORTIA**

### **8:33C-5.1 Required services**

(a) The MCHC shall develop and implement a three-year regional perinatal and pediatric plan which takes into consideration all certificate of need application criteria, set forth in this chapter, approved but unimplemented certificate of need applications, and the levels of care offered by licensed providers of perinatal and pediatric services. The regional perinatal and pediatric plan shall be updated and approved by the Department annually. The three year regional perinatal plan and the annual update, as appropriate, shall be submitted to the Department on or before October 1 of every year.

(b) The MCHC shall develop and implement a system for discharge planning, infant follow-up and child health care coordination in the MCHC region. This system shall assure post-discharge continuity of care and shall be linked to necessary resources, such as:

1. Primary care services for all children in need of a primary care provider;
2. Referral to follow-up services for high risk infants. Guidelines, compliance with which is not mandatory, are available from the Department of Health and Senior Services, Regional Services Program, PO Box 364, Trenton, New Jersey 08625-0364, telephone (609) 292-5616.
3. Case management provided in coordination with Special Child and Adult Health Services County Case Management Units, as appropriate;
4. Home follow-up; and
5. Counseling services to parents, especially those experiencing perinatal or infant loss including, when appropriate, referral to the Sudden Infant Death Syndrome Resource Center established pursuant to N.J.S.A. 52:17B-88.

(c) The MCHC, in conjunction with the designated Regional Perinatal Center shall establish, coordinate and monitor a regional transport system. This system shall include written policies and procedures for triage of mothers, neonates and/or infants to a facility designated and licensed to provide the most appropriate level of care, in accordance with formal letters of agreement between the MCHC and its Regional Perinatal Center(s) and Community Perinatal Centers. The regional transport system and any subsequent modification(s) thereof shall be reviewed and approved by the Department prior to implementation. The regional transport system plan shall include:

1. Documentation of current transport capabilities with actual transport numbers based on the most recent year available at the time licensure application is made;
2. A planned system to insure appropriate maternal-fetal, neonatal and/or infant transport to facilities designated and licensed to provide appropriate levels of advanced care;
3. A planned system for back transports of mothers, neonates and infants, where appropriate;
4. Written policies and procedures for maternal-fetal, neonatal and infant transports which specify that the most at-risk mothers, neonates and infants shall be triaged and transported, as soon as possible, to the facility designated and licensed to provide the most advanced appropriate level of care within the region, in accordance with these rules and N.J.A.C. 8:43G-19;
5. Written policies and procedures governing circumstances when the maternal and child health service region does not have a bed or bassinet available to accommodate a transport in accordance with the regional maternal-fetal, neonatal and infant transport plan; and
6. Documentation of existing pediatric transport capabilities.

(d) The MCHC shall provide or coordinate on-going, area wide professional education for all perinatal and pediatric service providers in the region, including, at least, regularly scheduled regional conferences. The MCHC shall provide or coordinate consumer education which is demographically appropriate to the region. The MCHC shall have in place a mechanism to assess the effectiveness of the regional education program annually.

(e) The MCHC shall establish a region-wide program for quality assurance which includes total quality improvement and regular collection and analysis of data which is designed to identify the nature and severity of health-service problems. The program and any subsequent modification(s) thereof shall be reviewed and approved by the Department prior to implementation. As part of the quality assurance program, the MCHC shall recommend, implement and monitor corrective action, based upon the data collected. The MCHC's plan for the region-wide program shall address at least the following:

1. A uniform regional system for automated data collection;
2. Management of the program by a specific subcommittee of the MCHC, which subcommittee shall meet at least quarterly;
3. Policies and procedures for collecting, abstracting and reporting data to the appropriate subcommittee, for use in quality assurance activities; and
4. Criteria for review of perinatal and pediatric statistics and pathology, including, but not limited to the following:

- i. Transports with death;
- ii. Non-compliance with rules regarding birth weight and gestational age;
- iii. Cases in which no prenatal care was received;
- iv. All maternal deaths;
- v. All fetal deaths over 2,500 grams not diagnosed as having known lethal anomalies;
- vi. Selected pediatric deaths and/or adverse outcomes (to be specified in the plan);
- vii. Immunization of children two years of age in accordance with the provisions of N.J.A.C. 8:57 (Communicable Diseases); and
- viii. Admissions for ambulatory care sensitive diagnoses in children.

#### **8:33C-5.2 Data reporting requirements**

(a) The MCHC shall carry out the following responsibilities in accordance with N.J.S.A. 26:1A-37 through 37.4.

1. Upon request, the MCHC shall submit any documents and/or data which are required to be kept, to the Department, including, but not limited to formal letters of agreement between the MCHC member facilities;
2. The MCHC shall collect, maintain and submit to the Department data required by its obligations to comply with N.J.A.C. 8:33E-5.1(a) through (e); and
3. On or before October 1 of every year, the MCHC shall submit to the Department, for review and approval, an annual budget plan for the next calendar year. The budget plan must identify all projected salary and non-salary costs necessary to implement both the regional perinatal and pediatric plan and the functions listed in N.J.A.C. 8:33C-5.1. The budget plan must also identify revenue sources adequate to support the expenses submitted therein, which shall include the amounts to be paid the MCHC by all member hospitals.

(b) The MCHC shall be required to comply with patient confidentiality requirements set forth in N.J.A.C. 8:43G (Hospital Licensing Standards), and N.J.S.A. 26:1A-37 through 37.4.



### **8:33C-5.3 Compliance with laws and rules**

(a) If the MCHC provides direct medical services and/or nursing services, it shall comply with the applicable sections of N.J.A.C. 8:43A, Manual of Standards for Licensure of Ambulatory Care Facilities.

(b) The MCHC shall comply with patient confidentiality requirements as specified in Hospital Licensing Standards, N.J.A.C. 8:43G. The MCHC shall assure that all patient care records it possesses will be kept confidential. Information in the patient's records shall not be released to anyone outside the MCHC without the patient's approval, unless another health care facility to which the patient was transferred requires the information, or unless the release of the information is required and permitted by law, a third-party payment contract, a medical peer review, or the Department. The MCHC may release anonymous data about the patient for studies containing aggregated statistics.

(c) The MCHC shall comply with applicable Federal, State, and local laws, rules, and regulations.

(d) No MCHC shall be operated by any person convicted of a crime relating adversely to the person's capacity to operate the MCHC.

### **8:33C-5.4 Policy and procedure manual**

(a) The MCHC shall develop, implement, and, in accordance with the schedule set forth therein, periodically review a policy and procedure manual governing the organization and operation of the MCHC. Each review of the manual shall be documented. The manual shall include at least the following:

1. A written statement describing the MCHC's objectives and the services provided by the MCHC, both directly and by MCHC members;
2. An organizational chart delineating the lines of authority, responsibility, and accountability for the administration of the MCHC;
3. Definition and specification of the MCHC's business hours, hours of operation, and full working week;
4. A system of patient referral to sources of primary, secondary and tertiary health care; and
5. Policies and procedures for the maintenance of personnel records for each employee, including, at minimum, the employee's name, previous employment, educational background, credentials, license number with effective date and date of expiration (where applicable), professional certification (where applicable), verification of credentials, records of physical examinations, job description, records of staff orientation and staff education, and job performance evaluations.

(b) The policy and procedure manual shall be available in the main office of the MCHC and accessible at all times to representatives of the Department, MCHC staff, MCHC members and the public.

#### **8:33C-5.5 Reportable events**

(a) The MCHC shall report to the Department the termination of employment of the administrator/executive director and the name and qualifications of that person's replacement, within seven days of the termination.

(b) The MCHC shall report to the Department whenever a hospital loses status as a member in good standing, within 15 days of the delinquency.

#### **8:33C-5.6 Notices**

The MCHC shall conspicuously post a notice in its main office, that the following information is available within the facility during business hours:

(a) All waivers granted by the Department, if any;

(b) The list of deficiencies, if any, from the last annual licensure inspection and certification survey report and the list of deficiencies, if any, from any valid complaint investigation during the past 12 months;

(c) The names and addresses of the members of the governing authority; and

(d) The hours of operation and the business hours of the MCHC.

## **SUBCHAPTER 6. GOVERNING AUTHORITY**

### **8:33C-6.1 Appointment of the MCHC governing authority**

The MCHC shall have a governing authority appointed in accordance with N.J.A.C. 8:33C-2.3, which shall assume legal responsibility for the management, operation, and financial viability of the MCHC.

### **8:33C-6.2 Responsibility of the governing authority**

(a) The governing authority shall be responsible for at least the following:

1. Adoption and documented review of written by-laws, or their equivalent, in accordance with a schedule established by the governing authority;
2. Development and documented review of all policies and procedures, in accordance with a schedule established by the governing authority;
3. Establishment and implementation of a system whereby patient and staff grievances and/or recommendations, including those relating to patient rights, can be identified. This system shall include a feedback mechanism through management to the governing authority, specifying what action was taken;
4. Establishment of a governing authority meeting schedule, as well as a meeting schedule for the governing authority's committees, and/or their equivalents. The governing authority shall conduct the meetings, and shall keep formal minutes of all of its meetings and its committee meetings;
5. Delineation of the duties of the officers of any governing authority committees, or their equivalent. When the governing authority establishes committees, or their equivalent, their purpose, structure, responsibilities, and authority, and the relationship of the committee to other entities within the MCHC, shall be fully documented;
6. Establishment of the qualifications of members and officers of the governing authority; the procedures for electing and appointing officers; and the terms of service for members, officers, and committee chairpersons or their equivalent; and
7. Development of an allocation and collection system to ensure adequate revenue from members of the MCHC who have been assessed dues, in accordance with the by-laws, necessary to fund the budget approved by the Department in accordance with N.J.A.C. 8:33C-5.1(e).

## **SUBCHAPTER 7. ADMINISTRATION**

### **8:33C-7.1 Appointment of administrator/executive director**

The governing authority shall appoint an administrator or executive director who shall be accountable to the governing authority. The administrator or executive director shall meet all of the qualifications set forth in N.J.A.C. 8:33C-7.3.

### **8:33C-7.2 Administrator/executive director's responsibilities**

(a) The administrator shall be responsible for at least the following:

1. Planning and administration of the managerial, operational, fiscal, and reporting components of the MCHC, as determined by the governing authority; and
2. Establishing and maintaining liaison relationships with the Department, with MCHC staff and service departments, with member support services departments, with member community resources departments, and with consumers.

### **8:33C-7.3 Staff qualifications**

(a) Each MCHC shall have on staff:

1. An administrator/executive director who has a master's degree and at least three years of administrative or supervisory experience in health care planning or administration or finance, at least one year of which shall have been in maternal and child health services;
2. A registered professional nurse with a master's degree in nursing, public health or public administration from an accredited college or university and certification by the National Certification Corporation for the Obstetric, Gynecologic and Neonatal Nursing Specialties or the American Nurses Association, and two years of experience in clinical maternal and child nursing; and
3. Adequate staff to perform the functions set forth in N.J.A.C. 8:33C-5.1 and implement the regional perinatal and pediatric plan, including, but not limited to:
  - i. A research/data specialist with training in research methods and experience in data analysis; and
  - ii. A community outreach coordinator with a bachelor's degree from an accredited college or university with one year of experience in community outreach.